IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AETHER THERAPEUTICS INC., Plaintiff, v. ASTRAZENECA AB, ASTRAZENECA PHARMACEUTICALS LP, NEKTAR THERAPEUTICS, and DAIICHI SANKYO, INC., Defendants.	Civil Action No. 20-381-MN
AETHER THERAPEUTICS INC., Plaintiff, v. REDHILL BIOPHARMA INC., Defendant.	Civil Action No. 21-248-MN

DEFENDANTS' OPENING BRIEF IN SUPPORT OF THEIR MOTION FOR JUDGMENT ON THE PLEADINGS ON AETHER'S CLAIMS FOR INFRINGEMENT OF U.S. PATENT NOS. 8,883,817, 9,061,024, AND 8,748,448 UNDER FEDERAL RULE OF CIVIL PROCEDURE 12(c)

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I. Nature and Stage of Proceedings

Pursuant to Federal Rule of Civil Procedure 12(c), Defendants AstraZeneca AB, AstraZeneca Pharmaceuticals LP (collectively, "AstraZeneca"), Nektar Therapeutics ("Nektar"), and Daiichi Sankyo Inc. ("Daiichi Sankyo") (collectively, the "AstraZeneca Defendants") respectfully request that the Court grant judgment on the pleadings on Plaintiff Aether Therapeutics Inc.'s ("Aether's") claims for infringement under the doctrine of equivalents of U.S. Patent Nos. 8,883,817 and 9,061,024 in C.A. No. 20-381 (the "AstraZeneca Action"). On the same grounds, Defendant RedHill Biopharma Inc. ("RedHill") respectfully requests that the Court grant judgment on the pleadings on Aether's claims for infringement under the doctrine of equivalents of those patents and U.S. Patent No. 8,748,448 in C.A. No. 20-248 (the "RedHill Action"). Collectively, the '817, '024, and '448 Patents are referred to as the "unit dosage patents."[1]

These cases are two related patent-infringement actions. Aether filed its operative Complaint (First Amended Complaint) in the AstraZeneca Action on June 11, 2020, and its operative Complaint (First Amended Complaint) in the RedHill Action on June 8, 2021. C.A. No. 20-381, D.I. 19; C.A. No. 21-248, D.I. 33. Defendants in these cases answered on January 22, 2021, and July 14, 2021, respectively. C.A. No. 20-381, D.I. 52-54; C.A. No. 21-248, D.I. 40. The Court coordinated the cases for purposes of *Markman* proceedings, issued its claim construction order from the bench following the claim construction hearing on August 30, 2021, and issued a written order incorporating the transcript of its bench order on September 17, 2021. C.A. No. 20-381, D.I. 99; C.A. No. 21-248, D.I. 59.

[1] The '448 Patent, although initially asserted against the AstraZeneca Defendants in the AstraZeneca Action, was dismissed by stipulation. C.A. No. 20-381, D.I. 77.

II. Summary of Argument

Each asserted claim of the unit dosage patents recites a "unit dosage of an analgesic composition" comprising, at a minimum, an "opioid agonist" and "neutral opioid antagonist." The Court construed the "unit dosage" limitations to mean "that the opioid agonist and neutral opioid antagonist (and pharmaceutically acceptable carrier, where appropriate) are co-formulated in a single dosage form, *i.e.*, in one unit." D.I. 99, at 1, 13.[2]

Aether does not dispute that Movantik®, the accused product, contains an opioid antagonist as the sole active ingredient. It does not contain an opioid agonist. Following the Court's *Markman* ruling, Aether now acknowledges that Movantik® cannot literally infringe the unit dosage patents and has agreed to dismiss its claims for literal infringement of those patents. However, in supplemental infringement contentions served days after the Court's *Markman* order, Aether asserted that the unit dosage patents were infringed under the doctrine of equivalents, arguing that "directing a dosage of the antagonist, while also separately taking an agonist" is equivalent to the claimed "unit dosage of an analgesic composition." Ex. A1, at 1, 5; Ex. A2, at 1; Ex. A2, at 5, 50, 54; Ex. A3, at 1, 4.

The dedication-disclosure doctrine precludes Aether's assertion of equivalency as a matter of law. Under that doctrine, disclosed, but unclaimed embodiments are dedicated to the public and cannot be recaptured under the doctrine of equivalents. Here, the relevant record clearly establishes that the unit dosage patents disclose the asserted equivalent—"directing a dosage of the antagonist, while also separately taking an agonist"—by describing "co-administration" and "separate but overlapping administration." The plain language of the patents, attached and incorporated into the operative Complaints, and Aether's binding

[2] Unless otherwise noted, all citations refer to C.A. No. 20-381.

admissions, are dispositive. Indeed, the Court recognized in its *Markman* order that the unit dosage patents' "specifications distinguish between instances where the agonist and antagonist are formulated together in a 'unit dosage' versus administered as separate doses," D.I. 99, at 9, and ruled that co- and separate but overlapping administration were outside the scope of the claims, D.I. 99, at 1, 13. Consequently, Aether cannot rely on equivalency, and judgment on those claims is warranted.

III. Statement of Facts

Aether asserts infringement based on Movantik®. C.A. No. 20-381, D.I. 19, D.I. 19-1, at 209; C.A. No. 21-248, D.I. 33, D.I. 33-1, at 210. It is not disputed that Movantik® contains an opioid antagonist, but does not contain an opioid agonist. C.A. No. 20-381, D.I. 19 ¶¶ 80-89; C.A. No. 21-248, D.I. 33, at ¶¶ 51-60. Aether's operative Complaints accuse Defendants of infringing four patents. C.A. No. 20-381, D.I. 19; C.A. No. 248, D.I. 33. Three of those patents are at issue here.

A. The '448, '817, and '024 Patents Disclose Separate But Overlapping Administration.

By Aether's own admission, the unit dosage patents' specifications[3] disclose three alternative methods of administration: (1) co-formulation of the agonist and antagonist, (2) co-administration of the agonist with the antagonist, and (3) separate but overlapping administration of the agonist and antagonist.[4] The "Summary of the Invention" in each of the unit dosage patents states: "The present invention teaches the use of an opioid agonist/neutral opioid

[3] The '817, '024, and '448 Patents claim priority to the same provisional application and their specifications contain overlapping material. C.A. No. 20-381, D.I. 19-1, at 31, 94, 146.

[4] In its supplemental infringement contentions regarding the doctrine of equivalents, Aether apparently treats co-administration of separate doses of the agonist and antagonist, and separate but overlapping administration of the agonist and antagonist components, as the same for purposes of its assertions. Ex. A1, at 1, 5; Ex. A2, at 1; Ex. A2, at 5, 50, 54; Ex. A3, at 1, 4.

antagonist co-formulation, co-administration of the agonist with the antagonist, or separate but overlapping administration of the agonist with the neutral antagonist." D.I. 19-1, at 68, 127, 183 ('448 Patent, 2:56-63; '817 Patent, 2:13-19; '024 Patent, 2:57-64).

Aether cites these passages in its operative Complaints, admitting that each of the unit dosage patents "directly teaches 'co-administration of the agonist with the antagonist, or separate but overlapping administration of the agonist with the neutral antagonist.'" C.A. No. 20-381, D.I. 19 ¶¶ 282, 311, 340, 369 (citing '448 Patent, 2:55-63); ¶¶ 396, 422, 448, 474 (citing '817 Patent, 2:12-18); ¶¶ 498, 528, 558, 588 (citing '024 Patent, 2:57-64); C.A. No. 21-248, D.I. 33 ¶ 97 (citing '448 Patent, 2:55-63), ¶ 121 (citing '817 Patent, 2:12-18), ¶ 142 (citing '024 Patent, 2:57-64).

Significantly, the patents distinguish the claimed "unit dosages" from co- and separate but overlapping administration. *See, e.g.*, D.I. 19-1, at 80, 195 ('448 Patent, 25:13-20; '024 Patent, 25:17-24 ("[I]n some embodiments, the invention provides a co-administration of an opioid agonist (i.e., an opioid analgesic) and a neutral antagonist. . . . In some embodiments, the opioid antagonist and the neutral antagonist are co-formulated together (e.g., in a unit dosage).").

The specifications also describe examples involving both co- or separate administration of an agonist (e.g., hydrocodone, morphine, or methadone) and antagonist (e.g., 6β-naltrexol, 6β-naltrexamide, or naltrexone), D.I. 19-1, at 82-91, 135-40, 197-206 ('448 Patent, Ex. 1-2, 4-9; '817 Patent, Ex. 1-2, 4-7; '024 Patent, Ex. 1-2, 4-9); and co-formulations, D.I. 19-1, at 85, 137-38, 200-01 ('448 Patent, Ex. 3; '817 Patent, Ex. 3; '024 Patent, Ex. 3).

B. Aether Has Admitted That the '448, '817, and '024 Patents Disclose Separate But Overlapping Administration.

During *Markman* proceedings, Aether argued that the "unit dosage" limitations should be construed to encompass "co-administration, or separate but overlapping administration" of an

agonist and antagonist. D.I. 71, at 7-8; D.I. 88, at 28-29. In so doing, Aether admitted repeatedly that the unit dosage patents disclose co- or separate but overlapping administration in addition to unit dosage administration:

- "***The specification allows for three different forms of administration:*** (1) co-formulation; ***(2) co-administration; and (3) separate but overlapping administration.***" D.I. 88, at 54.

- "***[T]he specification clearly teaches and defines*** the use of an 'opioid agonist/neutral opioid antagonist co-formulation, ***co-administration of the agonist with the antagonist, or separate but overlapping administration of the agonist with the neutral antagonist.***" D.I. 88, at 55 (citing '448 Patent, 2:56-66, 3:1-3; '817 Patent, 2:13-26; '024 Patent, 2:57-67, 3:1-4).

- "Construing 'unit dosage' only as a co-formulated product disregards the ***other two embodiments defined by the specification—co-administration, and separate but overlapping administration.***" D.I. 88, at 55 (citing '448 Patent, 2:56-66, 3:1-3; '817 Patent, 2:13-26; '024 Patent, 2:57-67, 3:1-4).

- "Plaintiff cites to a ***number of studies contained within the specifications of the patents-at-issue that show separate administration*** of the opioid agonist and neutral opioid antagonist." D.I. 88, at 32-33 (citing '817 Patent, 17:41-44, 17:56-58, 18:60-63, 19:16-19, 23:17-19, 23:32-35, 23:57-59, 24:13-16, 24:36-39, 25:63-66, 26:12-14, 26:52-62, 27:12-15, 27:26-29, 27:36-39; 024 Patent, 42:35-41, 44:33-51).

- "[Defendants'] argument ignores the ***exemplary embodiments in the specifications that describe administering the agonist and antagonist separately*** . . ." D.I. 88, at 59-60 (citing '817 Patent, 5:21-23, 5:31-37, 5:63-6:3, 6:4-8, 6:12-13, 6:19-27, 6:30-33, 6:50-53; '024 Patent, 7:49-51, 7:59-67, 9:34-39, 9:43-47, 9:51-52, 9:62-10:3, 10:6-9, 10:27-30; '448 Patent, 7:49-51, 7:59-67, 9:34-39, 9:43-47, 9:51-52, 9:62-10:3, 10:6-9, 10:27-30).

- "Plaintiff points to ***four different examples*** in the '817 Patent ***where hydrocodone (opioid agonist) and 6β- naltrexol (neutral antagonist) were administered separately***. Similar examples involve 6β-naltrexamide or naltrexone as the neutral antagonist. The '024 Patent and '448 Patent cite the same examples, along with another two examples illustrating separate administration of the opioid agonist and neutral antagonist to humans. D.I. 88, at 57-58 (citing'817 Patent, 17:41-44; 17:56-58; 18:60-63; 19:16-19; 23:17-19, 23:32-35, 23:57-59, 24:13-16, 24:36-39, 25:63-66, 26:12-14, 26:52-62, 27:12-15, 27:26-29, 27:36-39; '024 Patent, 42:35-41, 44:33-51; 448 Patent, 42:17-23, 44:29-47).

At the *Markman* hearing, on August 30, 2021, Aether repeated many of those arguments. Ex. B, at 9:4-12; 11:14-19; 12:23-13:2.

C. The Court's *Markman* Order Established That the Patents Disclose, But Do Not Claim, Separate But Overlapping Administration

In its *Markman* order, the Court rejected Aether's proposed construction and construed the "unit dosage" limitations to "mean that the opioid agonist and neutral opioid antagonist (and pharmaceutically acceptable carrier, where appropriate) are co-formulated in a single dosage form, *i.e.*, in one unit." D.I. 99, at 13.

The Court explained that, although the unit dosage patents' specifications disclosed embodiments involving co- and separate but overlapping administration, they were alternatives to the claimed "unit dosage" co-formulation embodiments:

> Moreover, I think that ***the specifications distinguish between instances where the agonist and antagonist are formulated together in a "unit dosage" versus administered as separate doses. As a general matter, the patents distinguish between co-formulation, co-administration and separate but overlapping administration of the agonist and neutral antagonist***. Although Plaintiff argues that this means all three options fall within the meaning of "unit dosage," I'm unpersuaded, particularly because there is no clear language indicating that. Moreover, ***the '024 and '448 Patents provide that in some embodiments, co-administration of the opioid agonist and antagonist occurs, whereas in other embodiments, "the invention includes a co-formulation product comprising an opioid agonist and a neutral antagonist (e.g., in a unit dosage)."*** This suggests that co-administration and separate but overlapping administration is different from co-formulation in a "unit dosage."

D.I. 99, at 9-10 (emphasis added) (citations omitted).

IV. Argument

Aether's infringement claims under the doctrine of equivalents for the unit dosage patents fail as a matter of law. Aether's doctrine of equivalents theory rests on its assertion that "directing a dosage of the antagonist, while also separately taking an agonist" is equivalent to the claimed "unit dosage" co-formulations. As Aether's operative Complaints admit, and as recognized by this Court's *Markman* order, the unit dosage patents disclose separate administration of an opioid antagonist and opioid agonist. But the Court's *Markman* order also

holds that the separate administration embodiments are outside the scope of the claims. Accordingly, the doctrine of equivalents cannot be used to recapture such unclaimed embodiments under the dedication-disclosure doctrine.

A. Legal Standards

1. Federal Rule of Civil Procedure 12(c)

Rule 12(c) provides: "After the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." Rule 12(c) determinations in this Court are subject to Third Circuit law. *Eagle Pharms., Inc. v. Slayback Pharma LLC*, 958 F.3d 1171, 1174-75 (Fed. Cir. 2020). "A motion for judgment on the pleadings based on the defense that the plaintiff has failed to state a claim is analyzed under the same standards that apply to a Rule 12(b)(6) motion." *Revell v. Port Auth. of N.Y.*, 598 F.3d 128, 134 (3d Cir. 2010). Under those standards, judgment is appropriate where, as here, the moving party "clearly establishes [that] there are no material issues of fact" and that it "is entitled to judgment as a matter of law." *Sikirica v. Nationwide Ins. Co.*, 416 F.3d 214, 220 (3d Cir. 2005) (citing *Soc'y Hill Civic Ass'n v. Harris*, 632 F.2d 1045, 1054 (3d Cir. 1980)).

In deciding a Rule 12(c) motion, a court may consider "matters of public record, orders, exhibits attached to the complaint and items appearing in the record of the case." *Almirall, LLC v. Torrent Pharms., Ltd.*, C.A. No. 20-1373-LPS, 2021 WL 3021947, at *3 (D. Del. July 13, 2021) (quoting *Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1384 n.2 (3d Cir. 1994)). Thus, where, as here, the operative Complaints attach and rely on copies of the patents, the Court may properly consider them. *See, e.g., In re Bendamustine Consol. Cases*, C.A. No. 13-2046-GMS, 2015 WL 1951399, at *1 (D. Del. Apr. 29, 2015) ("[T]he '190 and '863 patents [and] their file histories . . . are all properly before the court, even at this preliminary stage."). It may also properly consider the *Markman* order and the parties' filings. *See, e.g., Almirall*, 2021

WL 3021947, at *3; *Lecat's Ventriloscope v. MT Tool & Mfg.*, C.A. No. 16-5298-RC, 2018 WL 3651592, at *3 (N.D. Ill. Aug. 1, 2018) (considering *Markman* order in Rule 12(c) decision).

Applying these standards, multiple courts in this District have recognized that Rule 12(c) justifies judgment on legally defective claims for infringement under the doctrine of equivalents, including based on the dedication-disclosure doctrine. *See, e.g.*, *Eagle Pharms.*, 958 F.3d at 1174-78 (affirming, under Third Circuit law, grant of Rule 12(c) motion based on dedication-disclosure doctrine); *Amgen Inc. v. Coherus BioSciences Inc.*, 931 F.3d 1154, 1159-61 (Fed. Cir. 2019) (same for prosecution history estoppel); *Almirall*, 2021 WL 3021947, at *4 (granting Rule 12(c) motion based on prosecution history estoppel); *In re Bendamustine Consol. Cases*, C.A. No. 13-2046-GMS, 2015 WL 1951399, at *1-3 (D. Del. Apr. 29, 2015) (same based on dedication-disclosure doctrine).

2. The Dedication-Disclosure Doctrine

The dedication-disclosure doctrine precludes application of the doctrine of equivalents where "a patent drafter discloses but declines to claim subject matter." *Eagle Pharms.*, 958 F.3d at 1175 (quoting *Johnson & Johnson Assocs. v. R.E. Servs.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (en banc)). "By preventing a patentee from recapturing unclaimed subject matter, the dedication-disclosure doctrine reinforces 'the primacy of the claims in defining the scope of the patentee's exclusive right.'" *Id.* To determine whether the doctrine applies, courts "ask whether the specification discloses unclaimed subject matter with 'such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed.'" *Id.* (quoting *PSC Comput. Prods., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004)). If it does, "the patent owner cannot prevail on its doctrine of equivalents infringement claim based on that equivalent." *Id.* The dedication-disclosure doctrine "requires only that the specification disclose the unclaimed matter 'as an alternative to the relevant claim limitation.'"

Id. at 1176 (quoting *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1378 (Fed. Cir. 2005)).

B. Defendants Are Entitled to Judgment on the Pleadings on Aether's '817, '024, and '448 Patent Infringement Claims Under the Doctrine of Equivalents.

The operative Complaints, exhibits, and other items properly considered in the context of this Rule 12(c) motion clearly establish that the dedication-disclosure doctrine precludes Aether's assertion of the unit dosage patents under the doctrine of equivalents as a matter of law. The patents' specifications clearly disclose co- and separate administration as alternatives to the claimed "unit dosages." *See, e.g.*, D.I. 19-1, at 68, 127, 183 ('448 Patent, 2:56-63; '817 Patent, 2:13-19; '024 Patent, 2:57-64); *supra* Section III.A. Indeed, as this Court held in its *Markman* order, the unit dosage patents' "specifications distinguish between instances where the agonist and antagonist are formulated together in a 'unit dosage' versus administered as separate doses." D.I. 99, at 9. Despite disclosing those alternative methods of administration, however, the patents claim only those in which "opioid agonist and neutral opioid antagonist (and pharmaceutically acceptable carrier, where appropriate) are co-formulated in a single dosage form, *i.e.*, in one unit." D.I. 99, at 13. Aether therefore cannot rely on the doctrine of equivalents to recapture embodiments involving co- or separate but overlapping administration. *See, e.g.*, *Eagle Pharms.*, 958 F.3d at 1174-78; *Johnson & Johnson*, 285 F.3d at 1051-55; *In re Bendamustine*, 2015 WL 1951399, at *1-3.

In correspondence pre-dating this motion, Defendants identified to Aether the dedication-disclosure doctrine, and explained in detail why it foreclosed Aether's equivalency contentions. Ex. C, at 2-3. Aether responded that it nonetheless would continue to pursue equivalency. The complete extent of Aether's reasons for doing so were stated in its letter as follows:

> We argued to the court that the other embodiments were disclosed

> and claimed. The Court disagreed and found they were not claimed and not supported by the specification. As such, these embodiments were neither disclosed nor disclaimed.

Ex. D, at 1.

Aether's response flies in the face of reality. This Court's ruling, and the passages in the specification on which the Court relied, could not be clearer. As the Court held, the unit dosage specifications expressly "distinguish between co-formulation, co-administration and separate but overlapping administration of the agonist and neutral antagonist." D.I. 99, at 9 (citing '817 Patent, 2:12-15; '024 Patent, 2:57-60; '448 Patent, 2:56-59). That holding plainly recognizes that each of these methods of administration were disclosed, and that they were alternatives to each other. The Court further held that "the '024 and '448 Patents provide that in some embodiments, co-administration of the opioid agonist and antagonist occurs, whereas in other embodiments, 'the invention includes a co-formulation product comprising an opioid agonist and a neutral antagonist (e.g., in a unit dosage).'" D.I. 99, at 9 (citing '024 Patent, 17:24-28; '448 Patent, 17:34-8). Far from rejecting the proposition that the unit dosage patents failed to disclose embodiments involving co- and separate but overlapping administration, the Court relied on that premise as a basis for its construction.

Aether's position is also belied by the admissions that it made in its operative pleadings. *See supra* Sections III.B-III.C. That the Court disagreed with Aether's proposed claim construction of the "unit dosage" limitations does not mean that Aether can simply disavow those admissions as if they never existed (not that Aether has taken any formal steps to do so as of the date of this filing). Under Third Circuit law, Aether's allegations in its Complaints that the unit dosage patents "directly teach 'co-administration of the agonist with the antagonist, or separate but overlapping administration of the agonist with the neutral antagonist,'" *supra* Section III.B, are "formal concessions" that "are binding upon the party making them." *Parilla*

v. IAP Worldwide Servs., VI, Inc., 368 F.3d 269, 275 (3d Cir. 2004). And the fact that, until now, Aether agreed and advocated that the patents disclosed co- and separate but overlapping administration speaks volumes about the merits of its position.

Rule 12(c) unquestionably authorizes the Court to grant judgment on Aether's claims here. In *Eagle Pharmaceuticals*, for example, the Federal Circuit affirmed Chief Judge Connolly's Rule 12(c) ruling that the dedication-disclosure doctrine precluded application of the doctrine of equivalents where the specification "repeatedly identifie[d]—without qualification—ethanol as an alternative pharmaceutically acceptable fluid" to the claimed ingredient and contained no suggestion that such disclosures were "limited to certain formulations, or that they do not extend to the claimed formulation." 958 F.3d at 1176. In *Amgen*, the Federal Circuit likewise affirmed Judge Stark's Rule 12(c) ruling of prosecution history estoppel where the applicant "clearly and unmistakably surrendered [the] unclaimed [disclosure] during prosecution." 931 F.3d at 1160. And in *In re Bendamustine*, Judge Sleet granted judgment on the pleadings under Rule 12(c) where the patents "disclosed but did not claim the additional organic solvents" that the plaintiff sought to recapture. 2015 WL 1951399, at *3.[5]

Here, Aether's claims for infringement are even more untenable than those other courts have addressed under Rule 12(c). This Court has already held that the unit dosage patents disclose, but do not claim the very embodiments that Aether seeks to recapture under the doctrine of equivalents. D.I. 99, at 7-13. There is nothing left to decide. Judgment on the

[5] *See also Almirall*, 2021 WL 3021947, at *4 (granting Rule 12(c) motion where "the prosecution history clearly and unmistakably demonstrates that the applicant surrendered Carbopol® as an equivalent for the claimed A/SA"); *Cumberland Pharms. Inc. v. InnoPharma, Inc.*, C.A. No. 12-618-LPS, 2013 WL 5945794, at *3 (D. Del. Nov. 1, 2013) (same where applying doctrine of equivalents "would vitiate the 'free from a chelating agent' claim limitation").

pleadings is therefore appropriate.

V. Conclusion

For the foregoing reasons, Defendants respectfully request that the Court grant judgment on the pleadings for all Defendants on Aether's claims for infringement of the '817 and '024 Patents under the doctrine of equivalents. Additionally, RedHill respectfully requests that the Court grant judgment for RedHill on Aether's claim for infringement of the '448 Patent under the doctrine of equivalents.

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